SENATE BILL REPORT SB 5660

As of January 31, 2022

Title: An act relating to access to psilocybin services by individuals 21 years of age and older.

Brief Description: Concerning access to psilocybin services by individuals 21 years of age and older.

Sponsors: Senators Salomon, Lovelett, Kuderer, Pedersen, Saldaña, Trudeau and Wellman.

Brief History:

Committee Activity: Health & Long Term Care: 2/02/22.

Brief Summary of Bill

- Directs the Department of Health (DOH) to administer a regulatory system for supported adult use of psilocybin, beginning January 1, 2024.
- Directs DOH to create standards for manufacturing, testing, packaging, and labeling psilocybin products with the assistance of a Psilocybin Advisory Board and other government agencies.
- Allows a person over the age of 21 to purchase psilocybin products in a psilocybin service center and undergo a preparation session, administration session, and integration session under the supervision of a trained facilitator.
- Restricts employment in the psilocybin industry to licensed or permitted individuals over the age of 21.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Kevin Black (786-7747)

Background: Psilocybin is a naturally occurring, psychoactive chemical compound

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produced by over 200 species of mushrooms, many of which grow natively in the Pacific Northwest. Ingestion of psilocybin may produce changes in perception, mood, and cognitive processes common to other psychedelic drugs, a class of naturally occurring and laboratory-produced substances which includes mescaline, LSD, MDMA, and DMT. Psilocybin may be extracted and may be synthesized by chemical processes. Many who have taken psilocybin describe having a mystical or spiritual experience, during a trip that lasts for four to six hours. Possession, manufacture, and delivery of psilocybin is illegal under both state and federal law.

Early research into the therapeutic benefit of psychedelic drugs was conducted in the 1950s and 1960s. After a fallow period, research into psilocybin made a strong resurgence. In 2019, the U.S. Food and Drug Administration designated psilocybin therapy as a "breakthrough therapy" in studies looking into its potential as a treatment for severe treatment-resistant depression and major depressive disorder. Other studies suggest therapeutic uses for psilocybin in the treatment of addiction, PTSD, obsessive-compulsive disorder, anxiety, and nicotine dependence, among other conditions. A number of U.S. cities have recently adopted resolutions expressing support for deprioritizing criminal enforcement of laws relating to psilocybin and other psychedelic drugs, including the City of Seattle in October 2021.

On November 3, 2020, Oregon voters adopted Oregon Measure 109, a ballot initiative supported by 55.75 percent of the voters. Oregon Measure 109 legalizes psilocybin in Oregon law and establishes a regulatory structure similar to the one proposed in this legislation. Oregon is scheduled to begin issuing licenses related to psilocybin on January 2, 2023.

Summary of Bill: The bill as referred to committee not considered.

Summary of Bill (Proposed Substitute): Overview. Beginning January 2, 2024, the Department of Health (DOH) must license psilocybin service centers (centers), psilocybin service facilitators (facilitators), psilocybin product manufacturers (manufacturers), and psilocybin testing laboratories. Under this regulated system, an individual who is at least 21 years of age may purchase psilocybin services from a licensed center. Psilocybin services include an administration session, in which the client consumes the drug at a center under the supervision of a facilitator, and must remain at the center until the facilitator certifies that the session is concluded.

The Psilocybin Advisory Board. A Psilocybin Advisory Board (Board) is established to provide advice and recommendations to DOH, consisting of at least 20 members appointed by the Governor. Board members must serve four year terms at the pleasure of the Governor. The Board must meet as least once every two months during the 18-month program development period starting July 1, 2022, and ending with the issuance of the first psilocybin licenses in January 2024.

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<u>Duties of the Department of Health.</u> DOH must develop rules which include minimum standards for manufacturing, transportation, delivery, advertising, and sale of psilocybin products. These rules must prohibit advertising that is appealing to minors, promotes excessive use, or promotes illegal activity. DOH may not require psilocybin products to be manufactured by means of chemical synthesis, prohibit the use of naturally grown mushrooms, or mandate the use of patented products or procedures. DOH must establish the maximum concentration of psilocybin permitted in a single serving of psilocybin and the number of servings permitted in a psilocybin product package.

DOH must adopt requirements, specifications, and guidelines for psilocybin preparation sessions, administration sessions, and integration sessions. DOH must develop rules for the conduct of centers and facilitators, and determine qualifications, training, and education and fitness standards for all psilocybin licensees. License fees must be calculated to cover but not exceed the cost of administration. DOH may immediately restrict, suspend, or refuse to renew a license based on probable cause that a licensee has purchased psilocybin products from an unlicensed source or has sold, stored, or transferred psilocybin products in an unauthorized manner. DOH may take any action necessary to prevent the diversion of psilocybin products from a licensee to an entity which is not operating legally under the laws of this state.

DOH must publish medical, psychological, and scientific studies and information relating to the safety and efficacy of psilocybin in treating behavioral health conditions.

Eligibility to Become a Client of a Psilocybin Service Center. A psilocybin client is not required to be diagnosed or have any particular medical condition to receive psilocybin services. The client must prove they are at least 21 years of age, complete and sign a client information form enabling the center to determine whether the client should participate in an administration session. The client information form must include information that may identify risk factors and contraindications, health and safety warnings, and disclosures required by DOH. Neither a center or facilitator is liable for reasonably relying on representations made by a client in a client information form. The client must attend a preparation session with a facilitator, which may but need not be held at a center, and may be held in person or remotely. After the administration session, the client may participate in an integration session, which may but need not be held at a center, in person or remotely.

Eligibility to Hold a Psilocybin License. All psilocybin licensees must be at least 21 years of age, undergo a fingerprint background check, and satisfy DOH they have completed required education and training and are competent and of good moral character. DOH may require applicants to disclose the names, addresses, and financial interests of each person involved in a psilocybin business. Individuals who handle psilocybin on behalf of a manufacturer must hold permits issued by DOH, proving they have complied with age verification and training requirements. A licensee or their employee is exempt from state criminal laws relating to psilocybin while complying with psilocybin laws and rules. A licensee may not retaliate or discriminate against whistleblowers.

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Psilocybin Service Facilitators. A facilitator must have at least a high school or equivalent education and pass an examination that has been approved, administered, or recognized by DOH. Examinations must be offered at least twice per year. DOH may not require a facilitator to have a degree from a university, college, or other institution of higher education. Facilitators must be trained in support skills which are affirming, nonjudgmental, culturally competent, and non-directive. They must receive training in client safety and how to interact with clients who may have behavioral health conditions. Training for facilitators must be modular, allowing pieces to be offered either separately or as part of a comprehensive package. DOH must formulate a code of professional conduct for facilitators, giving particular consideration to a code of ethics. A facilitator must renew their license annually. Until January 1, 2026, a facilitator must provide proof they have been a resident of the state for at least two years.

<u>Psilocybin Service Centers.</u> A center must have defined boundaries and may not be mobile. An individual may not have a financial interest in more than five centers. Administration sessions must be held at a center unless an exception applies allowing psilocybin services to be administered in the home of a client who is medically unable to travel to the center. Until January 1, 2026, at least 50 percent of the ownership shares of a center must be held by individuals who have been residents of the state for at least two years. A center must only sell psilocybin products tested by a laboratory licensed to test psilocybin.

A center may not disclose personally identifying information about a client except in the context of litigation, compliance with licensure requirements, or reporting a crime or evidence of criminal intent. DOH may require centers to maintain liability insurance.

Psilocybin Product Manufacturers. A manufacturer may not manufacture psilocybin products outdoors. An individual may have a financial interest in only one manufacturer. Until January 1, 2026, more than 50 percent of the shares in a manufacturer must be held by individuals who have been residents of the state for at least two years. A manufacturer must annually renew its license. DOH must create endorsements for different types of manufacturing activities, including a microtier manufacturing endorsement with lower license fees to reduce barriers to access, and allow manufacturers to hold multiple endorsements. DOH may adopt rules restricting the quantity of psilocybin products kept at the premises of a manufacturer. Labeling for psilocybin products must be clear, precise, and not be deceptive. DOH may prohibit the use of injurious or adulterated ingredients. Labels and packaging must include health and safety warnings, activation time, potency, serving size and number of servings included, and contents, to the extent applicable.

<u>Transfer of Psilocybin Products.</u> DOH must develop a system for tracking the transfer of psilocybin products between licensed premises using the system developed by the Liquor and Cannabis Board to track cannabis products. The system must prevent diversion of psilocybin products to other states, prevent substituting or tampering, and ensure an

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accurate accounting of production, processing, testing, and sale. Psilocybin products may only travel between licensed premises.

<u>Testing of Psilocybin Products.</u> DOH must establish standards in consultation with the Liquor and Cannabis Board and Department of Agriculture for testing psilocybin products to protect public health and safety. DOH may conduct random testing and inspections to determine the compliance of licensees.

<u>Psilocybin Regulation by Cities and Counties.</u> Cities and counties may adopt ordinances placing reasonable regulations on the operation of psilocybin businesses and where they may be located. An ordinance that prohibits a center or manufacturer from being located within a certain distance of another psilocybin business or school may not exceed a prohibition radius of 1000 feet. In the case of a school, the distance is reduced to 500 feet if there is a physical or geographic barrier capable of preventing children from traversing onto the premises. Authority to issue licenses related to psilocybin or to levy taxes and fees related to psilocybin is vested solely in the Legislature.

Social Opportunity Program. A social opportunity program is established at DOH to establish equity and help remedy harms resulting from historical injustice and the disproportionate and targeted enforcement of drug-related laws on poor and marginalized communities. To assist individuals who qualify as social equity applicants, DOH may provide technical assistance, including by establishing a partnership network, providing reduced license fees, and allowing applicants to receive points towards a license application score. A social opportunity applicant is defined as an entity or individual in which at least 51 percent of ownership and control come from a distressed area, or over half of its employees come from a distressed area, based on classifications made by government entities or on the local rate of participation in public assistance programs.

<u>Penalties.</u> DOH may impose civil penalties up to \$500 or \$5,000 per violation of psilocybin rules. Law enforcement officers may assist DOH in enforcing the rules. A person under the age of 21 who enters a psilocybin premises is guilty of a class 2 civil infraction. A person who produces false identification to misrepresent their age in connection with psilocybin is guilty of a misdemeanor. A person who makes psilocybin products available to a visibly intoxicated person is guilty of a civil infraction. To give a psilocybin product as a prize, premium, or consideration for a game of chance or skill is a class 1 civil infraction.

<u>Protections.</u> Physicians, physician assistants, advanced registered nurse practitioners, psychologists, social workers, mental health counselors, and marriage and family therapists must not be subject to arrest, prosecution, civil penalty, or adverse licensing action for recommending psilocybin to a patient. A psilocybin client is protected from criminal, civil, or adverse licensure action penalties for the mere use of psilocybin. Primary caregivers are protected for assisting a qualifying patient with the use of psilocybin within state laws. State and local government entities are immune from suit under state law for actions taken

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or omitted related to state psilocybin laws. Employers may not discriminate against employees for receiving psilocybin services absent visible impairment at work and may not test employees for psilocybin unless the employee exhibits clear, observable symptoms of impairment.

This legislation may be known and cited as the Washington Psilocybin Services Wellness and Opportunity Act.

Appropriation: None.

Fiscal Note: Requested on January 6, 2022.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: The bill contains several effective dates. Please refer to the bill.

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